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EXAMINER

WHALEY, PABLO S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/828,846

Applicant(s)

BINDER ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/24/06; 8/19/04</u> | 6) <input checked="" type="checkbox"/> Other: <u>IDS 1/24/05</u> |

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election with traverse of Group I drawn to Specie A (SLE) and Specie B (Scl-70), filed 12/27/2005, is acknowledged. Applicants' arguments that the search of the all species in groups A and B would not be burdensome has not been found to be persuasive, as the species of autoimmune diseases are separately classified and published, and the species of antigens are drawn to chemically distinct compounds as discussed in the previous office action. Any search requires a search of non-patent literature, U.S. patent publications, U.S. patents, as well as foreign patent literature. Therefore, the examiner maintains that it would be burdensome to search more than a single species of each group. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/27/2005.

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 1-31, as they read on the species of systemic autoimmune disease (SLE) and antigens (Scl-70).

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 8-12, 14-17, 18-21, and 25-31 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 1-5, 8-12, and 14-17 are directed to a computer-implemented process that does not recite either a physical

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transformation of matter nor a practical application. For example, instant claim 1 recites "applying a k-nearest neighbor process to the sample data." As this "k-nearest neighbor process" is merely a clustering algorithm, claim 1 does not result in a physical transformation of matter. However, computer implemented processes may be statutory where they recite a concrete, tangible, and useful result (i.e. a practical application). No actual, concrete result is recited in the claims, nor is any useful result "produced" in a tangible form useful to one skilled in the art. For these reasons, the claims are not statutory. See the Guidelines for Patent Eligible Subject Matter (USPTO, 1300 OG 142, Nov. 22, 2005).

Claims 18-21 and 25-31 are directed to a computer system configured to provide output data. The system is not limited to comprise any hardware element or combination of software and hardware such that it is interpreted to be a physical article of manufacture. Claim 18 recites the limitation of a "storage means" for storing a plurality of reference data sets. However, no actual description or definition for a "storage means" is provided in the Specification. Paragraphs [0012], [0022], and [0023] describe memory devices or modules; however, it is not clear that these are intended to be a description of a "storage means." It is noted that even where a "storage means" is interpreted to be a memory device or module, paragraph [0022] specifically states that the memory may be a *nonvolatile* or volatile medium, thus the "storage means" may be a nonphysical element such as a carrier wave. Further, claim 18 specifically limits the storage means to be one "for storing a plurality of data...". Paragraph [0025] of the Specification discloses that data can be stored in a "database table," thus the "storage means" of claim 18 may be merely a table containing data. For these reasons, the storage means is not interpreted to be a physical element of the computer "system" claimed. Further, it is not clear what relationship is intended between the "storage means" and the "means for" performing various functions also recited in the claims (See below). Reading the claims "in light" of the

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instant Specification, the computer system comprises either a list of instructions for performing various steps (i.e. a program) and some sort of memory medium, not necessarily having any relationship to the instructions; or it comprises a list of instructions and a database. A list of instructions (i.e. program) without any functionality to perform the instructions is not statutory subject matter. A database, even when carried on a physical medium, is nonfunctional descriptive material, and is not statutory subject matter. A combination of a database and a program does not render either statutory. For the reasons set forth above, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

CLAIM REJECTIONS - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-21 and 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 18 recites the limitation "storage means." Paragraphs [0012], [0022], [0023] of the Specification describe memory devices or modules. Paragraph [0025] of the Specification discloses that data can be stored in a "database table," thus the "storage means" of claim 18 may be merely a table containing data. As no specific definition of "storage means" is provided, the claims contain subject matter which

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is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 18 recite the limitation of "having an association." It is unclear whether the association is positive, negative, or otherwise. Also, it is unclear what parameters are to be considered and to what degree, in order to know whether a reference data set is "associated" with a particular SAD. Clarification is requested. Claims 2-17 and 19-31 are rejected as are dependent from Claims 1 and 18.

Claim 9 recites the limitation of "wherein storing includes receiving." As parent claim 8 confusingly does not recite "storing", but instead further limits the "receiving" step of claim 1, it is unclear what method step is intended to be limited by claim 9. Clarification is requested.

Claim 18 recites the limitation "storage means". As no "storage means" has been specifically described or defined by provided in the Specification, it is unclear whether a "storage means" is intended to be a memory, a data table, or otherwise. Furthermore, it is unclear what relationship is intended between a "storage means" and the various "means for" performing the functions recited in the claims. Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 11-14, 18-21, and 25-28 are rejected under 35 U.S.C. 103(a) as being made obvious by Thompson et al. (Lupus, 1993, 2, p.15-19), in view of Kim et al. (IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765) and Diamond et al. (Cytometry, 1994, 17, p.266-273)

Thompson et al. teach a method of identifying subsets of patients with systemic lupus erythmatosus (SLE) based on their autoantibody profile (Abstract). More specifically, Thompson et al. teach the following aspects of the instantly claimed invention:

- Multiple autoantibody profiles related to the systemic autoimmune disease SLE [Abstract], as in instant claims 1 (lines 5-8), 2, and 19.

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- Profile “Neg” representing a negative profile not associated with an SAD [Table I], which correlates to at least one reference data set associated with none of the SADs as in instant claim 1 (lines 8-9).
- Serum samples from 117 patients with levels for each of the autoantibody profiles [p.15, Materials and Methods], as in instant claim 1.
- Antibody profiles include SSA, SSB, centromere, Scl-70, Sm, nDNA, histone [Abstract], as in instant claims 4, 5, 20, and 21.
- Statistical analysis of data [Tables III and IV], which at a minimum suggests the data was input into a computer for storage as in instant claim 18.

Thompson et al. do not specifically teach the limitation of “applying a k-nearest neighbor process”, but do suggest the statistical analysis of differences between SLE subsets (p.16, lines 31-33).

Kim et al. teach a fast k-nearest neighbor (kNN) search algorithm based on ordered partitions (Abstract). More specifically, Kim et al. teach the following:

- Applying the kNN search algorithm to identify test sample elements that are associated with training sample elements [p.761, Section II, Search Procedure], as in instant claims 1 (lines 12-14) and 18.
- Determining a distance metric (r_i^2) associating test and training data distances at various “node” level coordinate values [p.763, col. 1 (lines 1-19)], which correlates to “concordance value” between sample and reference data as in instant claims 11-13 and 25-27. Note: Instant claim 13 (lines 5-8) are inherent to the search algorithm, as it is recursive [p.762, “Searching” Section]. Furthermore, wherein the training data is

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antibody data as taught by Thompson et al., the value r_i^2 is reasonably interpreted as a “disease” concordance value, as in instant claims 14 and 28.

- Distance threshold value d_k^2 [p.763, col. 1 (lines 4-6)], as in instant claims 11 and 25.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Thompson et al. with the k-nearest neighbor searching algorithm of Kim et al., where the motivation would have been to provide automated decision support in hospitals lacking specially trained individuals as taught by Diamond et al. (Abstract), resulting in the practice of the instant claimed invention with a reasonable expectation of success.

Claims 6-10 and 22-24 are rejected under 35 U.S.C. 103(a) as being obvious by Thompson et al. (Lupus, 1993, 2, p.15-19), in view of Kim et al. (IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765) and Diamond et al. as applied to claims 1-5 and 11-14, above, and further in view of Kopecky (Design and Implementation of the Internet-Based Medical Expert System ToxoNet, 1999, p.1-153)

Thompson et al., Kim et al., and Diamond et al. make obvious the method of identifying subsets of patients with systemic lupus erythmatosus (SLE) based on their autoantibody profile (Abstract), as previously discussed.

Thompson et al., Kim et al., and Diamond et al. do not teach the limitation of transmitting data across a network to a remote computer, and displaying the output data.

Kopecky teaches an internet-based medical expert system (ToxoNet) for providing

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automated decision support to the clinician. ToxoNet consists of three parts: ToxoServer, ToxoBuilder, and ToxoApplet [Results Section]. ToxoServer stores and retrieves patient data from the database [Section 3.2.2]. Data is transmitted across a network to ToxoApplet [Fig. 3.3], which correlates to instant claims 8. ToxoApplet generates interpretive diagnostic reports displayed on a GUI [Fig. 5.3], which correlates to instant claims 6 and 7. ToxoNet decision graphs denote interpretive test results of patient data compared to IgM titer reference values [Fig. 2.5], which correlates to reference data sent over the network as in instant claims 9 and 10. Kopecky teaches the use of a computer system with input/output devices and memory [p.60], as well as a monitor and printer [p.123], as in instant claims 22-24.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the invention of Thompson et al., Kim et al., and Diamond et al. on the internet-based decision support system of Kopecky, where the motivation would have been to use a World Wide Web interface integrated with a database to provide remote automated decision support (Kopecky [1.1]), resulting in the practice of the instant claimed invention with a reasonable expectation of success.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
3/6/06